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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,494	08/25/2003	Etan S. Chatlyne	ETH-5040	4244

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EXAMINER

ADAMS, AMANDA S

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,494	CHATLYNNE ET AL.	
	Examiner	Art Unit	
	Amanda Adams	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 25-42 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/16/06, 12/27/05, 5/5/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 10 is objected to because of the following informalities: Claim depends from claim 9, which is not an existing claim. Following a phone call with Sanjiv Chokshi on June 13, 2006, Claim 10 has been amended to depend from claim 8, however, consecutive renumbering of the claims should still be done. Appropriate correction is required.

1. Claim 2 is objected to because of the following informalities: "rotatable mounted" is incorrect grammar. The suggested change is to edit the phrase to read "rotatably mounted". Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The term "substantially" in claim 7 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The direction of the groove being substantially opposite to the direction of rotation of the winding tube is rendered indefinite.

1. Claim 36 recites the limitation "the suture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Biggs et al (US 6,599,311).

4. Biggs et al disclose a device for anchoring a surgical suture to a coiled helical member with winding means for winding a suture around a coiled helical member so that it is attached to at least one coil of the helical member (col. 22, lines 30-35).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2-7, 31-33, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggs et al in view of Jervis (WO 00/28902).

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7. Biggs et al disclose the invention substantially as claimed except for the following, which is taught by Jarvis:

8. Regarding claims 2 and 3, Jarvis teaches a casing in which the winding means is rotatably mounted to the casing (figure 7), and that is sized and shaped to be gripped by a surgeon (figure 7, [80]). In order for a tool to be useful to a surgeon, it would have a casing that can be gripped by the surgeon. Therefore it would have been obvious to apply the casing of Jarvis to the device of Biggs et al.

9. Regarding claims 4, 25, 35, Jarvis teaches a device wherein the winding means is a winding tube rotatable about an axis and movable in an axial direction in response to its rotational movement (page 8 lines 30-35). This provides the benefit of pushing the anchor distally towards its destination. Therefore it would have been obvious to have a winding tube that moves longitudinally in response to rotational movement on a device that secures a suture to a coiled helical component.

10. Regarding claim 5-7, 26, 27, and 36, Biggs et al disclose a winding tube that includes securing means for securing at least one portion of the suture thereto so as to cause the suture to wind about the helical member (figure 42A). However, Jarvis teaches a groove in the winding tube that is angled in a direction opposite to the direction of the winding tubes' rotation and that is capable of receiving at least one portion of the suture therein (page 5, lines 34-37). A groove such as this allows the suture to run the longitudinal length of the coiled helical member without exposing the entire helical member, thus protecting it until the surgeon is ready to deploy it. Therefore

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it would have been obvious to have a groove at an angle opposite to that of the rotational movement.

11. Regarding claims 31-33, Jervis teaches a support rod movable in a longitudinal direction in response to its rotational movement and that has a distal end shaped to engage a helical member by way of frictional fit (fig. 9 [20]). A connection between the coiled helical member and the support rod such as this is beneficial to the design of the device because it allows the helical member to be easily deployed. Therefore it would have been obvious to attach the helical member to the support rod with a frictional fit such as this one. It also would have been obvious to use the winding mechanism in the device of Biggs et al with a coiled helical anchor in place of the lung anchor they disclosed.

12. Claims 8, 10-15, 28-30, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggs et al in view of Jervis (WO 00/28902) and further in view of Bolduc et al (US 5,824,008).

13. Biggs et al in view of Jervis teach the invention substantially as claimed except for the following which is taught by Bolduc et al:

14. Regarding claim 8, Bolduc et al teach a winding tube with a plurality of screw threads and a casing with screw threads that mate with each other such that the winding tube is movable in an axial direction in response to its rotational movement (col. 9, lines 32-36). This provides the benefit of pushing the anchor distally towards its destination. Therefore it would have been obvious to have a winding tube that moves

longitudinally in response to rotational movement on a device that secures a suture to a coiled helical component.

15. Regarding claim 10 Bolduc et al teach a first gear engaged with a second gear, which is why the winding tube is rotatable in response to movement of the actuator (col. 9, lines 40-55). In order to translate movement from one direction to another, or from rotational to longitudinal it is well known to use gears. Therefore it would have been obvious to use a first and second gear in the actuator mechanism of the device.

16. Regarding claims 11-15, Jervis teaches a supporting means for supporting the helical member during winding of a suture around it (fig. 9, [20]), a guide tube rotatable mounted in a winding tube (the winding tube is disclosed by Biggs; figure 42A), a coiled spiral member at the end of the guide tube (Jervis; fig. 9, [60]) and a guide tube movable in an axial direction in response to rotation of the guide tube (page 8, lines 30-35). Regarding claim 15, Bolduc et al teach a guide tubes with helical grooves to accept a coiled helical member (figure 13). This provides the benefit of pushing the anchor distally towards its destination. Therefore it would have been obvious to have a winding tube that moves longitudinally in response to rotational movement on a device that secures a suture to a coiled helical component.

17. Regarding claim 28, 29, and 37, Bolduc et al teach a guide tube containing a coiled member at an end shaped to receive a helical member (col. 8, lines 58-60). This provides an additional guide for placement of the suture, and can further be considered as a helical member that the suture is meant to be wound about. Therefore it would have been obvious to have a coiled member at the end of the tube.

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18. Regarding claim 30 Bolduc et al teach a guide tube movable in an axial direction in response to its rotational movement (col. 9, lines 32-37). This provides the benefit of pushing the anchor distally towards its destination. Therefore it would have been obvious to have a winding tube that moves longitudinally in response to rotational movement on a device that secures a suture to a coiled helical component.

19. Regarding claims 38 and 39, Jervis teaches a device wherein the winding means is a winding tube rotatable about an axis and movable in an axial direction in response to its rotational movement (page 8 lines 30-35) and a support rod (figure 9, [20]). This provides the benefit of pushing the anchor distally towards its destination. Therefore it would have been obvious to have a winding tube that moves longitudinally in response to rotational movement on a device that secures a suture to a coiled helical component.

20. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biggs et al in view of Bolduc et al (US 5,824,008).

21. Biggs et al disclose the method including anchoring a suture to an anchor (col 24, lines 45-50), but fail to disclose the anchor being a coiled helical member. However, Bolduc et al teach that a helical member can be supported relative to a winding tube, and provides structural components for a suture to be wound about the helical member in a helical path (figure 13), wherein the winding tube is movable in an axial direction in response to its rotational movement (col. 9, lines 32-36), and the helical member is positioned in a coiled spiral member of a guide tube (figure 13). Winding a suture about a coiled helical shaped anchor prior to its deployment simplifies the implantation procedure for the surgeon, and a helical shape of the anchor increases its driving force

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into and stability within bone. Therefore it would have been obvious to perform this method with the suture winding steps disclosed by Biggs et al and the helical components as provided by Bolduc et al.

Allowable Subject Matter

22. Claims 16-24 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art discloses or suggests all of the limitations of claim 16. The closest prior art is that disclosed by Bolduc et al (figure 13) with a helical groove on the interior of the guide tube, but there are no lobes. Claims 17-24 are allowable because they depend from claim 16.

Conclusion

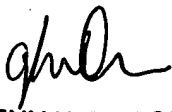
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

asa ASA 7/10/06


GLENN K. DAWSON
PRIMARY EXAMINER